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#19

OCT 22 1995

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Re: CPI® Ventak® P2 AICD System

FDA Docket No. 95E-0183

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. Re. 34,879, reissued March 14, 1995. The application was filed on May 8, 1995, under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office on the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. 156(d)(2)(A).

Gerald A. Dost
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

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